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March 5, 2012

The Honorable Leonard P. Stark
United States District Court
For the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *The Research Foundation of State University of New York et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 09-184-LPS
Mylan Pharmaceuticals Inc. v. Galderma Laboratories, Inc., et al.,
C.A. No. 10-892-LPS

Dear Judge Stark:

We write on behalf of Galderma pursuant to D. Del. LR 7.1.2(b) to bring to the Court's attention a new case related to the issue of Galderma's remedy in view of the Court's decision that Mylan's generic version of Oracea[®] infringes the asserted claims of U.S. Patent No. 7,749,532 ("the Chang Patent"). In particular, this new case squarely addresses a question raised by the Court during the February 17, 2012 hearing, during which the Court asked Galderma's counsel whether an ANDA lacking a Paragraph IV certification may give rise to an act of infringement under 35 U.S.C. § 271(e)(2). *See* Feb. 17, 2012 Hearing Tr. at 27:4-7.

Last week, in a Hatch-Waxman case brought in this District, Judge Robinson issued a Memorandum Order ruling that plaintiff Cephalon may maintain an action under 35 U.S.C. § 271(e)(2) against defendant Sandoz on its two patents-in-suit covering Cephalon's branded product Fentora[®], even though Sandoz ***had not filed Paragraph IV certifications*** with respect to those patents, and even though both patents-in-suit ***issued more than a year after*** the submission of Sandoz's ANDA.¹ *See Cephalon, Inc. v. Sandoz, Inc.*, C.A. No. 11-821-SLR (D.Del. March 1, 2012) (Ex. 1) at 2. Specifically, Judge Robinson (1) denied Sandoz's motion to dismiss Cephalon's complaint for lack of subject matter jurisdiction, concluding that "jurisdiction under § 271(e)(2) has been established," and (2) denied Sandoz's motion under Fed. R. Civ. P. 12(b)(6) to dismiss Cephalon's complaint for failure to state a claim of infringement under § 271(e)(2). *See* Ex. 1 at 10-13 & n.10.

¹ Pursuant to FDA regulation, Sandoz was not required to file a Paragraph IV certification on either of Cephalon's patents-in-suit, as both patents were Orange Book listed later than 30 days after their issuance. *See* Ex. 1 at 2.

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In her Memorandum Order, Judge Robinson expressly rejected Sandoz's arguments based on *Eisai v. Mutual*,² stating that she disagreed with the *Eisai* court's "sweeping conclusion that the absence of a Paragraph IV certification limits, as a matter of law, the court's subject matter jurisdiction under . . . 35 U.S.C. § 271(e)(2)" Ex. 1 at 10. According to Judge Robinson, *Eisai* was merely a case in which "the patent holder's conduct was so egregious that its ability 'to take advantage of § 271(e)(2)' was forfeited." *Id.* Accordingly, despite the absence of any Paragraph IV certifications on Cephalon's patents-in-suit, Judge Robinson ruled that subject matter jurisdiction existed based on § 271(e)(2), and that Cephalon's complaint had adequately stated a claim of infringement under § 271(e)(2). *See id.* at 12-13.

As argued by Galderma, Mylan has infringed the Chang Patent under 35 U.S.C. § 271(e)(2)(A), regardless of whether Mylan's ANDA for a generic version of Oracea[®] contained a Paragraph IV certification with respect to the Chang Patent. Accordingly, Galderma submits that the Court should grant the statutorily-mandated remedy of § 271(e)(4)(A) that resets the effective date of approval of Mylan's ANDA to a date no earlier than the expiration of the Chang Patent, as well as grant the permanent injunctive relief requested by Galderma pursuant to § 271(e)(4)(B) and § 283.

Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

JBB/dlb

Enclosures

cc: Clerk of Court (Via Hand Delivery; w/ encl.)
Richard L. Horwitz, Esquire (Via Electronic Mail; w/ encl.)
David Steuer, Esquire (Via Electronic Mail; w/ encl.)
Gerald J. Flattmann, Jr., Esquire (Via Electronic Mail; w/ encl.)

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Eisai Co. v. Mutual Pharm. Co., No. 06-3613, 2007 WL 4556958 (D.N.J. Dec. 20, 2007).